



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 3, 2020

Heidi Popelka
Senior Regulatory Specialist II
Ecolab Inc.
1 Ecolab Place
St. Paul, MN 55102

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: XHC-S
EPA Registration Number: 1677-255
Application Date: March 25, 2020
Decision Number: 561080

Dear Ms. Popelka:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

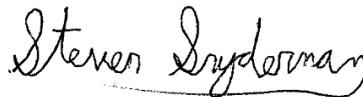
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is large non-enveloped and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Poliovirus 1 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

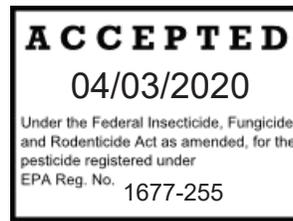
Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label



[Note to reviewer. Wording in brackets is considered optional.]

XHC-S

ONE-STEP DISINFECTANT / HARD SURFACE DISINFECTANT / VIRUCIDE* / VIRUCIDAL* / SPORICIDE ON HARD NON-POROUS SURFACES/ FUNGICIDE / NON-FOOD CONTACT SANITIZER

For use in [Hospitals], [Hospital Compounding Pharmacies], [Compounding Pharmacies], [Clean Rooms], [Controlled Areas], [Pharmaceutical Manufacturing Facilities], [Biomedical Facilities], [Biotechnology Facilities], [Medical Device Facilities],[Medical Device Manufacturing Facilities], [Life Science Laboratories],[Industrial Facilities]

Active Ingredient:

Sodium Dichloroisocyanurate.....53.0%**

Other Ingredients.....47.0%

Total:.....100.0%

[**Available Chlorine: 34.2%]

**KEEP OUT OF REACH OF CHILDREN
DANGER**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE: Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear (such as safety glasses or goggles) and protective clothing and gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. After product is diluted in accordance with the directions for use, protective eyewear is not required.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-328-0026

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage

Net Weight Contents: 170 g (6.0 oz)

PHYSICAL AND CHEMICAL HAZARDS: Contains strong oxidizing agent. Use only with clean dry utensils. Mix only with water. Do not mix with acids, ammonia or any other product or chemical. Can react to release chlorine or other hazardous gas.

ENVIRONMENTAL HAZARDS:

[For end use products packaged in containers with sizes less than 50 pounds.]
This product is toxic to fish and aquatic organisms.

[For end use products packaged in containers with sizes of greater than or equal to 50 pounds.]
This pesticide is toxic to birds, fish, and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

[(Enter product name) is decontaminated by gamma irradiation for use in controlled or aseptic areas.]

DIRECTIONS FOR USE

Read the label before using

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

USE: Empty all contents into 10 liters (2.64 gal) of water of suitable quality for the environment [such as] [water for injection][deionized water][USP water pharma grade] in which it is to be used to create a ≥ 5000 ppm (as available chlorine) solution. Stir the solution several times. When entirely dissolved, the solution is ready to use. Use standard procedure to wet surfaces entirely.

USE: This product is designed specifically as a [one-step] disinfectant [cleaner][Virucide*] [fungicide] [sanitizer][Sterilant] for use in hospital / manufacturing locations in areas such as: (NOTE TO REVIEWER: use sites to be selected from table below):

Hospitals	Hospital Compounding Pharmacies	Compounding Pharmacies
Clean Rooms	Controlled Areas	Pharmaceutical Manufacturing Facilities
Pharmaceutical Manufacturing Facilities	Biomedical Facilities	Biotechnology Facilities
Industrial Facilities	Healthcare Institutions	Biopharmaceutical
Biopharmaceutical Manufacturing Facilities	Medical Device Manufacturing Facilities	Diagnostic Manufacturing Facilities
Life Science Facilities	Animal Life Science Facilities	Pharmacies
Biomedical technology	Comparative Medicine	Laboratory Facilities

	Facilities	
Research Facilities	Biotechnology Facility	

Use on hard non-porous surfaces [in] [or] [on]: (NOTE TO REVIEWER: surfaces to be selected from table below):

Aseptic Filling Rooms	Gowning Rooms	General Manufacturing Areas
Isolators	Tables	Counters
Machinery	Floors	Walls
Hard, non-porous surfaces only	Non-porous hard surfaces only	Transfer disinfection
Laminar Flow benches	Shelves	Transfer Hatches
Carts	Ceilings	Countertops
(Biosafety Level) (BSL) hoods	Equipment	Laminar flow curtains
Hoods	Laboratory benches	Products in non-porous packaging for transfer disinfection.
Anywhere contamination control is required for hard, non-porous surfaces		

This product is compatible with [the listed materials] (NOTE TO REVIEWER: may select surfaces from list below). If the product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

316 Stainless Steel	304 Stainless Steel	Aluminum
PVC coated mild steel	Acrylic	Vinyl
Trespa	PVC	

[DISINFECTION] [ONE-STEP CLEANING/DISINFECTION] [COMBINATION DISINFECTION AND CLEANING] [HARD SURFACE DISINFECTION]:

When prepared as directed this product is a one-step disinfectant cleaner on hard, non-porous surfaces in clean rooms and controlled areas [according to the AOAC Use Dilution Test modified] [in the presence of 5% blood serum]. For heavily soiled areas, a pre-cleaning step is required. Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wiper or by soaking so as to wet all surfaces thoroughly. All surfaces must remain wet for a minimum of 5 minutes and then either allow to air dry or wipe dry with a [sterilized] cloth or wiper. When used as directed at a 5 minute contact time, this product is effective against:

Staphylococcus aureus (ATCC 6538)
Pseudomonas aeruginosa (ATCC 15442)
Escherichia coli (ATCC 11229)

[The diluted solution is stable for 24 hours.][Prepare a fresh solution daily.]

FOR USE AS A VIRUCIDE*

Prepare the use solution according to label instructions. For heavily soiled areas, a pre-cleaning step is required. Apply solution to hard, non-porous surfaces in clean rooms and controlled areas with a mop, cloth, [sponge], [brush], [scrubber] or disposable wiper by soaking so as to wet all surfaces thoroughly. All surfaces must remain wet for the required contact time indicated in the directions for use. Allow surfaces to air dry or wipe dry with a [sterilized] cloth or wiper.

VIRUCIDAL* in 5 minutes against the following viruses [according to the Virucidal Qualification Test modified][in the presence of 5% blood serum]:

- *Herpes Simplex Type I Virus (Herpes) (ATCC VR-733)
- *Herpes Simplex Type II Virus (Genital Herpes) (ATCC VR-734)
- *Influenza A Hong Kong H3N2 Virus (ATCC VR-544)
- *Rhinovirus Type 37 (ATCC VR-1607)
- *Poliovirus 1 (ATCC VR-1562)
- *Adenovirus (ATCC VR-5)

FUNGICIDAL: in 5 minutes against *Trichophyton mentagrophytes* (ATCC 9533), *Candida albicans* (ATCC 10231) and *Penicillium chrysogenum* (ATCC 10003) on hard, non-porous surfaces [according to the AOAC Fungicidal Test] [modified in the presence of 5% blood serum].

SANITIZATION: Prepare use solution according to label instructions. This product is a hard surface sanitizer for pre-cleaned hard, non-porous, non-food contact surfaces in clean rooms and controlled areas. Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wiper or by soaking so as to wet all surfaces thoroughly. Allow to remain wet for a minimum of 3 minutes and then either allow to air dry or if desired wipe dry with a [sterilized] cloth or wiper. When used as directed at a 3 minute contact time, this product is effective against:

- Staphylococcus aureus* (ATCC 6538)
- Enterobacter aerogenes* (ATCC 13048)

DIRECTIONS FOR USE AS A SPORICIDE ON HARD, NON-POROUS SURFACES:

Use only on hard, non-porous surfaces. Clean the surface to be treated of debris or organic material. Prepare use solution according to label instructions. Apply use solution by immersion of objects in containers, by covering interior surfaces of containers, or by confining (e.g. rimmed) surfaces (e.g. floors, tables, counters) that permit a continuous layer of liquid to cover the surface for the required contact time of 5 hours This product is effective against *Clostridium sporogenes* (ATCC 3584) and *Bacillus subtilis* (ATCC 19659) spores. Remove used solution and entrapped soil with a clean, dry, sterile cloth. Do not use this product as a sterilant on medical devices.

STORAGE & DISPOSAL

DO NOT CONTAMINATE WATER OR FOOD OR FEED BY STORAGE OR DISPOSAL

PESTICIDE STORAGE: Keep this product in a tightly sealed container. Store in a cool, dry, well ventilated area away from heat or open flame. In case of decomposition, isolate container (if possible) and flood area with large amounts of water to dissolve all material before discarding the container.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING AND DISPOSAL: Non-refillable container. Do not reuse or refill this container. Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

[Lot Number / Batch Code XXXXXX
EXPIRY: Day/Month/Year]

US EPA Reg. No. 1677-255
US EPA Est. No.: 001677-GBR-001

Manufactured by:
Ecolab Inc.
370 Wabasha Street N.
St. Paul, MN 55102-1390
USA

Made in Great Britain

[See [back], [side], [other] label [panel] for [complete][additional] [directions for use][precautionary statements] [and] [first aid]

[Refer to the (MSDS)(SDS) for additional product hazard information]

Optional Claims (Marketing Claims)

- [Gamma Irradiated] [Disinfectant][Unit Dose] [Concentrate][tablets][product]
- [Unit Dose] [Concentrate][disinfectant][solution][product][for hard, non-porous surfaces][for use in clean rooms and controlled areas.][Contains 17 tablets.]
- [Unit Dose] [Concentrate][hard, non-porous surface][disinfectant][solution]
- [Gamma Irradiated] [Soluble unit dose concentrate tablets] to make up [10 liters] [2.64 gallons] of ready-to-use [product] [solution]
- [Gamma Irradiated] [Soluble unit dose concentrate tablets]
- [Active Chlorine] [Concentrate][Tablet][Disinfectant][product]
- Disinfectant [concentrate][solution]
- [This] [product][disinfectant][tablet][active chlorine disinfectant][Active Chlorine Concentrate] [Active Chlorine Tablet] has broad spectrum activity, [controlling microbial contamination likely to be found in a clean room environment,] [including difficult bacterial spores]
- Easy to use
- [This] [product][single unit dose][Disinfectant][Tablet] [Active Chlorine Disinfectant] [Active Chlorine] [Active Chlorine Concentrate] [Active Chlorine Tablet] [contains 17 tablets][of 10 grams each.]
- [This] [product][single unit dose][Disinfectant][Tablet] [Active Chlorine Disinfectant] [Active Chlorine Concentrate] [Active Chlorine Tablet], [compromising 17 x 10 g tablets,] minimizes handling prior to dilution.
- [This] [product][single unit dose][Disinfectant][Tablet] [Active Chlorine Disinfectant][Active Chlorine Concentrate] [Active Chlorine Tablet] also assists correct usage by reducing the risk of dilution errors.
- Ideal for use with [the Klercide][Ecolab]Mopping System
- [This] [product][single unit dose] [Disinfectant][Tablet] [Active Chlorine Disinfectant][Active Chlorine Concentrate] [Active Chlorine Tablet] is non-corrosive in use [so it can be used in most clean room [cleaning][and][disinfecting] applications]
- Cost effective
- A unit dose means there is less unused product to discard.
- There is less unused product to discard.
- There is no need for filtration prior to use
- Dilution allows treatment of large areas
- [This] [product][single unit dose][Disinfectant][Active Chlorine Disinfectant][Active Chlorine Concentrate] consists of a [container][pot][tub] of 17 tablets of [sodium dichloroisocyanurate (NaDCC)] [NaDCC] [in an effervescent base], [which forms a solution containing approximately 0.5% (5000ppm) available chlorine when diluted in [10 liters][2.64 gallons] [of water]
- [This] [single unit dose] [Tablet] [Active Chlorine Tablet]of [sodium dichloroisocyanurate (NaDCC)] [NaDCC] forms a solution containing approximately 0.5% (5000ppm) available chlorine when diluted in [10 liters][2.64 gallons] [of water]
- Each tablet contains 5 [g][grams] of [sodium dichloroisocyanurate (NaDCC)] [NaDCC] in a total tablet weight of 10 [g][grams]
- Broad spectrum of antimicrobial activity [including spores]

- It has broad spectrum of antimicrobial activity [including spores and both enveloped and non-enveloped viruses]
- No additional activators are required
- It is suitable for cleaning and disinfecting large areas such as floors, walls and ceilings.
- It is supplied in a [container][pot][tub] containing 17 x 10 [g][grams] tablets for dilution with [10 liters] [2.64 gallons] of water [of suitable quality for the environment in which it is to be used]
- [This] [single unit dose] [Tablet] [Active Chlorine Tablet] readily dissolve
- Each [container][pot][tub] is filled in a Grade D (ISO Class 8) cleanroom and double bagged, before irradiation at no less than 25 kGy.
- [This] [product][single unit dose][Disinfectant][Tablet][Active Chlorine Disinfectant][Active Chlorine Concentrate] [Active Chlorine Tablet] is gamma irradiated
- [This] [product][single unit dose][Disinfectant][Tablet] [Active Chlorine Disinfectant][Active Chlorine Concentrate] [Active Chlorine Tablet] is double bagged [and gamma irradiated]
- Broad Spectrum Activity
- Broad Spectrum Activity, bactericidal, sanitizing, fungicidal and virucidal activity
- Sporicide on hard, non-porous surfaces
- [Sporicide] [on hard, non-porous surface] disinfectant [(tablets)]
- Bactericidal Activity
- Fungicidal Activity
- Virucidal Activity
- Sanitizing Activity
- [This] [product][single unit dose][Disinfectant][Tablet] [Active Chlorine Disinfectant][Active Chlorine Concentrate] [Active Chlorine Tablet] can be used as part of a rotation with other disinfectants
- Application Area: For use on floors, walls and hard, non-porous surfaces [in clean rooms and controlled areas]
- For use on floors, walls and hard, non-porous surfaces [in clean rooms and controlled areas]
- **[USE:]** [Tip one pot of 17 tablets into 10 liters (2.64 gal) of water of suitable quality for the environment in which it is to be used.] [The solution will effervesce.][Mix gently and use immediately][Diluted liquid can be applied directly onto a non-porous hard surface using a cleanroom mop, such as the Klercide Mopping System, or a cleanroom wipe.]
- [Where residues must be totally eliminated, then wipe down with water of suitable quality.][It can be used as part of a rotation with other disinfectants].
- [Use disinfectants safely.][Always read the label and product information before use.]

Manufacturing claims:

- Certificates of analysis [and certificate of gamma irradiation] with every batch
- [This] [concentrate][product] is manufactured in clean rooms for use in clean rooms.
- [This] [concentrate][is made in accordance to the principles of Good Manufacturing Practices (GMP)]



Emerging Viral Pathogens

“This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.”

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large, Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label</i>
Enveloped virus	Poliovirus 1 (ATCC VR-1562)
Large, non-enveloped virus	Poliovirus 1 (ATCC VR-1562)

Acceptable claim language:

[XHC-S] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [XHC-S] can be used against [name of emerging virus] when used in accordance with the directions for use against Poliovirus 1 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus.] [XHC-S] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Poliovirus 1 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.